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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,401	04/26/2000	Hiroyuki Yuyama	2000 0523A	1206

7590 02/28/2007  
Wenderoth Lind & Ponack LLP  
2033 K Street NW  
Suite 800  
Washington, DC 20006

EXAMINER
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GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/559,401

Applicant(s)

YUYAMA ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19, 21-32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 21-32, and 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/06 has been entered.

***Response to Amendment***

2. In the amendments filed 10/31/06 and 11/29/06, the following has occurred: claims 19, 21-25, and 27 have been amended and claims 20 and 33 have been canceled. Now, claims 19, 21-32, and 34-37 are presented for examination.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19, 21-32, and 34-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Claim 19 has been amended to indicate that "a decision unit is operable to decide a proper mixing order...based on the pH-values data." The originally filed specification indicates that a controller decides a mixing order of the injections based on pH-values data (see 3, lines 20-25 for example). The specification also describes that index pH-values could suggest that

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an injections may cause composition alteration (see page 10, lines 12-14). Finally, the specification describes moving certain medicaments to the forefront or to the rear based on whether they are transfusions or sole administration respectively, while "keeping the order of pH values as it is" (see page 19, lines 10-22). The only description of the order of pH-value is "the medicaments are rowed in order in accordance with the pH values thereof" (see page 19, lines 5-10). However, there is no description of whether they are "ordered" lowest-to-highest, highest-to-lowest, or some other order. There is also no other description of how a controller or decision unit would decide a mixing order based on the pH-values data. Therefore, One of ordinary skill in the art at the time of the invention would not have been adequately enabled to make and use the claimed invention. If this feature (a controller or decision unit to decide a proper mixing order based on pH-values data) was within the level of ordinary skill in the art at the time of the invention, the Examiner requests that Applicants provide documentation in support thereof.

#### ***Allowable Subject Matter***

6. The following is a statement of reasons for the indication of allowable subject matter: The primary reasons for the indication of allowable subject matter in claims 19, 21-32, and 34-37 is the inclusion of the limitations, in all of the claims which is not found in the prior art references, of a decision unit that is operable to decide a proper mixing order for a plurality of prescribed injections based on pH-values data that corresponds to the plurality of prescribed injections. The closest prior art (Teeple Jr., U.S. Patent No. 5,925,014 and Merki et al, U.S. Patent No. 5,002,055) teaches a decision unit that is operable to decide a proper mixing order of a plurality of prescribed injections (see Teeple, column 3, lines 54-56). The prior art also teaches deciding a mixing order of injections, based on pH-values, during an infusion (see

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Merki, column 3, lines 52-63). However, because the combined teachings of Teeple and Merki does not explicitly teach a decision unit that is operable to decide a proper mixing order for a plurality of prescribed injections based on pH-values data that corresponds to the plurality of prescribed injections, where the pH-values data are acquired before dosing the plurality of injections, the claims distinguish over the closest prior art.

7. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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2/20/07

  
**C. LUKE GILLIGAN**  
**PRIMARY EXAMINER**  
**TECHNOLOGY CENTER 3600**